SEP 2 9 2009

K092020

Section 6 – 510(k) Summary

510(k) Summary for Aadva Zr Coloring Liquid

Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 897-4042
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Date Prepared: June 12, 2009

Device Name:

Proprietary Name: Aadva Zr Coloring Liquid
Classification Name: Porcelain Powder
Device Classification: Class II, 872.6660
Produce Code: EIH

Predicate Devices:

Company	Device	K Number	Date Cleared
Vita Zahnfabrik	Vita In-Ceram YZ for InLab	K022996	10/9/02
3M ESPE	LAVA(TM) FRAME SHADE	K011394	6/29/01

Description of Device:

Aadva Zr Coloring Liquid is a liquid used for the complete or partial coloration of milled substructures before sintering. Aadva Zr Coloring Liquid is available in 8 shades.

Indications for use:
Aadva Zr Coloring Liquid is a liquid used for the complete or partial coloration of milled porcelain substructures before sintering

Substantial Equivalence:
The applicant device is substantially equivalent to the predicate devices in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 2 9 2009

Mark Heiss, D. D. S.
Director of New Business Development and Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

Re: K092020
Trade/Device Name: Aadva Zr Coloring Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: June 29, 2009
Received: July 6, 2009

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K092020

Device Name: Aadva Zr Coloring Liquid

Indications for Use: Aadva Zr Coloring Liquid is a liquid used for the complete or partial coloration of milled porcelain substructures before sintering.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Hurley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092020